Safety Survey Modification Form (use as advised by the Safety Office) (Version 2.0)

1.0 VA San Diego Healthcare System
Subcommittee for Research Safety
Application to Modify a Current Safety Survey

v. 20180606

1.1 Protocol Information

Principal Investigator:

(b) (6)

IRB Protocol #:

H120108

IACUC Protocol #:

Bench Protocol #:

Project #:

Protocol Title:

Integrated Approaches for Identifying Molecular Targets in Alcoholic Hepatitis

Protocol Nickname:

InTeam

Date Prepared:

10/16/2018

1.2 Modification Request: Indicate the nature of the requested change/s. Check all that apply.

- ☐ I am adding new hazards to this study that do not require a modification to the protocol (be sure the change is clearly defined in the Materials & Methods Section of the Safety Survey)
- ☐ I am adding IBC application information (rDNA/synDNA)
- ☑ SRS instructed me to update the Safety Survey
- ☐ SRS instructed me to update the Staff List with corrected hazard exposures
- ☐ SRS instructed me to update the Space Use Form
- ☐ Other

Identify Other Modification Type

2.0 Description of Modification

2.1 Description of changes: Briefly describe the requested changes. Details will be provided in the revised version of the Safety Survey.

Updating the Safety Survey to the newest version, to account for the processing of the human samples.

3.0 Attach the Requested Forms

3.1 Please revise and attach the updated Safety Survey or other forms here. If the changes to the Survey change the hazard exposures of any staff member, revise and attach an updated Staff List, even if it was not requested.

Note - be certain that the new version of the Safety Survey is attached. If updating the Staff List, do NOT change the study roles, just indicate the appropriate hazard exposures. If you need to change the role of a person, a staff change modification form is needed.

Show Rev.	Edit/ View	Version	Form Name
		3.5	Research Protocol Safety Survey * This form was part of this submission.
		2.4	Staff List * This form was part of this submission.

4.0 Submission

4.1 Attach additional documents (if any) here (e.g., Safety Data Sheets, Lab SOPs, Exposure Control Plans, Vector Maps, etc.):

Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.						

4.2 I certify that my research studies will be conducted in compliance with and full knowledge of federal, state, and local policies, regulations, and guidelines governing the use of biohazardous materials, chemicals, radiation, and physical hazards. I further certify that all technical and incidental workers involved with my research studies will be trained prior to study commencement of potential hazards, the degree of personal risk (if any), and instructions and training on the proper handling and use of biohazardous materials, chemicals, radioisotopes, and physical hazards. A chemical inventory of all hazardous chemicals is provided for local review. Appropriate Occupational Safety and health, environmental, and emergency response programs will be implemented on the basis of the chemical list provided.

◉ Agree ○ Disagree

4.3 Submit to Review Board:

Staff List (Version 2.4)

1.0 Protocol Identification

1.1 VASDHS - Research Protocol Staff List

v20140909

Principal Investigator:

(b) (6)

Title:

Integrated Approaches for Identifying Molecular Targets in Alcoholic Hepatitis

Project Number:

IRB Protocol Number:

H120108

IACUC Protocol Number:

Date Prepared:

10/16/2018

2.0 Staff List

2.1 Add a row to the table below for each study staff member

Person	Roles/Study Type (select all that apply)	Hazards (select all that apply)	Special Considerations (select all that apply)
(b) (6)	☐ PI ☐ Animal ☑ Human ☐ Bench ☐ Administrative Assistant (no human, animal, or hazards)	☑ Biological ☑ Chemical ☑ Physical ☐ Radiation ☐ No Hazards	☐ Co-Investigator ☑ Obtains Informed Consent (Human Studies Only) ☑ Has Human Subject Contact (Human Studies Only) ☑ Uses Sensitive Information (Human Studies Only)

Research Protocol Safety Survey (Version 3.5)

1.0 VA San Diego Healthcare System (664)
SRS/IBC Research Safety and Biosafety Application

v. 20180806

PI:

(b) (6)

Title:

Integrated Approaches for Identifying Molecular Targets in Alcoholic Hepatitis

IRB Protocol Number:

H120108

IACUC Protocol Number:

Bench Protocol Number:

Project Number:

Preparation Date:

10/16/2018

Note: The purpose of this form is to identify hazards to RESEARCH PERSONNEL (personnel as listed in section 3.0 of the protocol form) participating on this study. Responses to the following questions should be limited only to work performed as part of VA research by personnel on VA time, in VA space and/or using VA resources.

1.2 Please select one:

- ○ This protocol involves basic (non-clinical) laboratory/bench research (typically performed in research-dedicated space).
- ◉ This protocol is limited to human subject sample collection, diagnostic or clinical procedures or shipping of samples by research staff (Do not include research that is conducted solely in clinical space by clinical staff commensurate with normal clinical duties)
- ○ Protocol-related hazards are limited to human imaging procedures.
- ○ None of the above

2.0 Materials and Methods

2.1 a. Describe your materials and methods involving potential hazards to VA research staff. The description should be presented so that any associated hazards, including nucleic acid work, can be clearly understood by a non-scientist. If any work will be conducted at a non-VA location, it must be clear whether you are requesting VA approval for VA off-site research, or whether this is collaborative research being conducted under a different institution's authority/approval (e.g., work conducted in a UCSD assigned laboratory). Specify who will be handling or working with the hazards (e.g., clinical staff, research staff, etc.).

Note: All wet lab activities associated with this study must be described here.

Blood is collected by clinical phlebotomy staff. Stool, urine, and saliva are provided to research staff directly from the subjects. Research staff take the samples to the VA lab where they are prepared for shipment (blood is centrifuged for serum and plasma collection, and all samples frozen and shipped; all samples are labeled with study code). (b) (6) will collect stool, serum and plasma samples and hand-carry them to his UCSD lab for analysis. Sample analysis conducted by (b) (6) is performed under UCSD approval.

3.0 Types of Hazards

3.1 DOES THE RESEARCH INVOLVE THE USE OF ANY OF THE FOLLOWING HAZARDS?

3.2 a. Biological Hazards I: Microbiological or viral agents, pathogens, toxins, poisons, venoms, and/or select agents as defined in Title 42 Code of Federal Regulations(CFR) 73?
[Does not include Human, Non-human primate or wild animal cell or tissue samples]

- (●) No
- ( ) Yes

3.3 b: Biological Hazards II: Human, non-human primate, or wild animal cell, body fluid, or tissue samples (including cultures, tissues, blood, other bodily fluids (e.g. saliva or urine) or cell lines)?

- ( ) No
- (●) Yes
- ( ) Collection of biologicals is limited to clinical setting, or research personnel do not have contact with the biological (e.g. subject-administered urine pregnancy test or saliva collection)

3.4 c. Biological Hazards III: Recombinant or Synthetic Nucleic Acid Molecules (e.g., rDNA, siRNA, PCR)

- (●) No
- ( ) Yes

3.5 d. Research Chemicals (e.g., toxic chemicals, flammable, explosive or corrosive agents; carcinogenic, mutagenic or corrosive chemicals; toxic compressed gases; acetylcholinesterase inhibitors or neurotoxins)

- ( ) No
- (●) Yes
- ( ) All work involving chemicals is limited to clinical setting (e.g., blood collection tubes, alcohol swabs, disinfectants) or research personnel do not have contact with the chemical (e.g. subject-administered urine pregnancy test)

3.6 e. DEA Controlled substances?

- (●) No
- ( ) Yes

3.7 f: Ionizing radiation?

(1) Radioactive Materials

- (●) No
- ( ) Yes

(2) Radiation generating equipment (e.g. irradiators, X-rays, etc.)

- (●) No
- ( ) Yes

3.8 g. Physical Hazards I: Non-ionizing radiation (e.g., ultraviolet light, Lasers (class 3b or 4), radiofrequency or microwave sources)?

- ( ) No
- (●) Yes

3.9 **h. Physical Hazards II: Are any of the people listed in the Research Protocol Staff List for this study in contact with any of the following: sharps or cutting devices (including microtomes), centrifuges or other electrical research/medical equipment, extreme temperatures (e.g., cold rooms, autoclaves or freezers), shipping biological materials including specialized shipping materials (e.g., dry ice), MRI, etc.**

- ○ No
- ◉ Yes

3.10 **i: Animals (note: automatically adds section for Physical Hazards)**

- ◉ No
- ○ Yes

3.11 **j. If the answer to <u>any</u> of these questions is YES, additional sections of this survey will apply.**

If <u>all</u> answers are NO, a documented review by the local Subcommittee on Research Safety is still required to verify that no hazards exist.

4.0 Cells, Body Fluids, and Tissue Samples

4.1 **a. Do personnel listed on Research Protocol come in contact with Human, Non-human primate or wild animal cells or tissue samples (blood, body fluids, organs, tissues, cell lines or cell clones)?**

- ○ No
- ◉ Yes

4.2 **Will personnel come in contact with blood from other animal species?**

- ◉ No
- ○ Yes

5.0 Biological Hazards II: Human, Non-Human Primate or Wild Animal Cells, Body Fluids, and Tissue Samples

5.1 **Use of Cells and Tissue Samples**

Please add new row

Specimen Type	Source	Source Detail (institution and protocol number)	Sample Type	Sample Detail (e.g., exact name/ID of any cell lines [e.g., 293 T cells], other species, urine, heart, etc.)	How is the sample stored (e.g., freezer, -80 freezer, in fixative, etc.)?
Human	Human Subjects	H120108	Body fluids (blood, serum, plasma, urine, etc.)	blood, stool, urine, saliva	-80 freezer

Use this space for any additional information related to the table detail

Please describe how you will obtain, transfer and use these samples

Blood is collected by clinical phlebotomy staff. Stool, urine, and saliva are provided to research staff directly from the subjects.
Blood is centrifuged to get serum and plasma, but everything else is just frozen and shipped

5.2 a. Will this tissue be injected or implanted into live animals?

○ Yes ◉ No

5.3 b. Specify the precautions employed to protect personnel:

All personnel shall follow Universal Precautions when handling blood, Other Potentially Infectious Material (OPIM), bodily fluids, cells and cell lines, and tissues from human, nonhuman primate or wild animals, and receive annual training on blood borne pathogens. All personnel shall use appropriate personal protective equipment as stated below. All surfaces and equipment used to handle blood are routinely decontaminated/disinfected as well as, after spills, splashes, or other potential contamination with a fresh solution of 10% household bleach followed with 70% ethanol. All plastic ware and glassware are disposed of in appropriate biohazards containers. Unused portion of the sample is decontaminated with a fresh solution of 10% household bleach and discarded in biohazard bags. All activities involving any of the above materials shall be handled under BSL-2 containment.

◉ Agree ○ Disagree

Please describe any changes to the above, or other precautions to be used for this study:

Human blood and other material of human, nonhuman primate or wild animal origin (including continuous cell lines) may contain HBV, HIV or numerous other pathogens known and unknown. As such, all personnel with occupational exposure to blood, cell lines and tissues (both human, non-human primate and wild animal origins) shall take annual training on blood borne pathogens, and should consult with Occupational Health for immunization recommendations. All personnel shall use appropriate personal protective equipment (PPE) including disposable gloves, coats, chemical splash goggles and/or face shield. PPE (i.e., protective clothing) shall be removed before leaving for non-laboratory areas. Eye and face protection must be disposed of with other contaminated laboratory waste or decontaminated before reuse. Disposable gloves shall be changed when contaminated, glove integrity is compromised, or when otherwise necessary. All personnel shall remove disposable gloves and wash hands when work with potentially infectious materials has been completed and before leaving the laboratory.

5.4 c. Are any biological samples or specimens transported or shipped outside the VA?

◉ Yes ○ No

Describe, including shipping processes (e.g. dry ice, rigid-sided container, etc.).

Research staff take the samples to the VA lab where they are prepared for shipment (blood is centrifuged for serum collection and frozen, all samples are labeled with study code). (b) (6) will collect stool, serum and plasma samples and hand-carry them to his UCSD lab for analysis. Sample analysis conducted by (b) (6) is performed under UCSD approval.

An MTA is required if biological samples are transferred out, and are not covered by another agreement already in place (e.g., industry-sponsored master protocol, CRADA or other contract). Note: samples sent to a UCSD laboratory require an MTA. However, if you are using the services of a CORE facility, an MTA is not required.

IATA training is required if samples will be packaged for transport via motor vehicle, air, vessel or rail (not required for hand-carried samples)

Is an MTA required?

◉ Yes ○ No

The MTA Template is located under the orange question mark in the upper right corner, in the section marked "IRB Forms." Return the completed form to Dr. Schulteis in Research Administration.

Is IATA Training needed?

◉ Yes ○ No

Help links to IATA/DOT Training opportunities:

If you need to complete IATA/DOT shipping training, there are multiple training modalities available to you:
Free training is available through any of these three channels:
1) VA Talent Management System TMS ("IATA 5" & "DOT 3")
2) Receiving Laboratories (i.e. ARUP online course),
3) Affiliate University- UC San Diego "Shipping Biological Sustance and Dry Ice" : **https://blink.ucsd.edu /facilities/services/shipping/hazardous/biological.html.**

At-cost training is also an option: see **http://www.saftpak.com/Training/training.aspx** as an example.

Please email completed training documentation to (b) (6) Training needs to be repeated every 2 years.

6.0 Hazardous Research Chemicals

6.1 a. I certify that I have provided an updated inventory of all chemicals used in my laboratory for this protocol to the Safety Office for entry into the online chemical inventory database. I will provide an updated inventory of all chemicals to the Safety Office twice yearly, and I will notify the Safety Office when new chemicals are received.

- (•) I agree

6.2 b. The research involves the use of any of the following chemicals:

Check all that apply

- [ ] Toxic Chemicals (including heavy metals)
- [x] Flammable, explosive, or corrosive chemicals
- [ ] Carcinogenic, mutagenic, or teratogenic chemicals
- [ ] Toxic compressed gases
- [ ] Acetylcholinesterase inhibitors or neurotoxins

6.3 c. Are personnel knowledgeable about the unique or "elevated risk" hazards posed by the chemical hazards listed above?

- ( ) No
- (•) Yes

7.0 Physical Hazards I: Nonionizing Radiation

7.1 a. Please indicate the type of non-ionizing radiation used in this study:

- [x] Ultraviolet Light
- [ ] Lasers (class 3b or class 4)
- [ ] Radiofrequency or microwave sources

7.3 b. Do Research Staff have contact with the non-ionizing radiation used in this study?

- (•) No
- ( ) Yes

8.0 Physical Hazards II

8.1 a. Does this study involve the use of MRI?

- ( ) Yes (•) No

8.2 **b. For studies that involve physical hazards such as animal handling, electricity, noise (e.g. MRI), or extreme temperatures, has the appropriate training and personal protective equipment been provided to personnel?**

(•) Yes ( ) No

9.0 Acknowledgement of Responsibility and Knowledge

9.1 **I certify that my research studies will be conducted in compliance with and full knowledge of federal, state, and local policies, regulations, and guidelines governing the use of biohazardous materials, chemicals, radiation, and physical hazards. I further certify that all technical and incidental workers involved with my research studies will be trained prior to study commencement of potential hazards, the degree of personal risk (if any), and instructions and training on the proper handling and use of biohazardous materials, chemicals, radioisotopes, and physical hazards. A chemical inventory of all hazardous chemicals is provided for local review. Appropriate Occupational Safety and health, environmental, and emergency response programs will be implemented on the basis of the chemical list provided.**

ANY CHANGES TO THE INFORMATION ON THIS FORM MUST BE SUBMITTED AS A PROTOCOL MODIFICATION

a) I recognize that I have responsibility for ensuring that ALL persons who enter my laboratory practice appropriate biosafety precautions.

b) I acknowledge that all persons working in or having access to spaces where this work is conducted must be instructed on the hazards associated with this project. All persons conducting this work (including my collaborators) have received instruction on the specific hazards associated with their work and the specific safety equipment, practices, and behaviors required during the course of their work and use of these facilities. The Institutional Biosafety Committee (IBC) or Subcommittee on Research Safety (SRS) may review my records documenting this instruction.

c) Any spill of hazardous/biohazardous material, any equipment or facility failure (e.g. ventilation failure), and/or any breakdown in procedure, which may result in potential exposure of laboratory personnel and/or the public to the said hazardous/biohazardous material must be reported to the Research Safety Office immediately.

d) Should an employee or co-worker become ill and exhibit symptoms consistent with an infection by an organism associated with my research, a report must be made to Employee Health and Research Administration immediately.

e) No new work, or changes to the work described in this form, will be conducted until appropriate approval is received from the SRS.

f) This work will be conducted using the biosafety precautions stated in the most current *CDC-NIH Biosafety in Microbiological and Biomedical Laboratories* and/or *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.

Having reviewed this application, I hereby certify its accuracy and accept the responsibilities stated above.

(•) Agree ( ) Disagree